

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>( Not for submission under 37 CFR 1.99)</i>	Application Number	10596851
	Filing Date	2006-06-27
	First Named Inventor	Brown
	Art Unit	1731
	Examiner Name	
	Attorney Docket Number	101260-1P US

**U.S.PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	3940386		1976-02-24	Szabo et al.	
	2	5574159		1996-11-12	Chang et al.	
	3	5681830		1997-10-28	Chang et al.	
	4	5807858		1998-09-15	Chang et al.	
	5	5854249		1998-12-29	Chang et al.	
	6	6130222		2000-10-10	Roberts et al.	
	7	6680318		2004-01-20	Brown et al.	
	8	6680321		2004-01-20	Roberts et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

	9	6696447		2004-02-24	Brown et al.	
	10	6784181		2004-08-31	Brown et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	8604584	WO		1986-08-14	Aktiebolaget Leo		<input type="checkbox"/>
	2	9107967	WO		1991-06-13	Janssen		<input type="checkbox"/>
	3	9204338	WO		1992-03-19	The Up-John Co.		<input type="checkbox"/>
	4	9315062	WO		1993-08-05	The Wellcome Foundation Limited		<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EL/

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

	5	9504051	WO		1995-02-09	The Wellcome Foundation Limited	<input type="checkbox"/>
	6	9723466	WO		1997-07-03	Astra Aktiebolag	<input type="checkbox"/>
	7	9828270	WO		1998-07-02	Astra Aktiebolag	<input type="checkbox"/>
	8	9828275	WO		1998-07-02	Astra Aktiebolag	<input type="checkbox"/>
	9	9933806	WO		1999-07-08	Ortho-McNeil	<input type="checkbox"/>
	10	0145637	WO		2001-06-28	AstraZeneca AB	<input type="checkbox"/>
	11	0146174	WO		2001-06-28	AstraZeneca AB	<input type="checkbox"/>
	12	0174805	WO		2001-10-11	AstraZeneca AB	<input type="checkbox"/>
	13	02094786	WO		2002-11-28	AstraZeneca AB	<input type="checkbox"/>
	14	02094794	WO		2002-11-28	AstraZeneca AB	<input type="checkbox"/>
	15	03029215	WO		2003-04-10	AstraZeneca AB	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

16	03094853	WO		2003-11-20	AstraZeneca AB et al.		<input type="checkbox"/>
17	2004041800	WO		2004-05-21	AstraZeneca AB		<input type="checkbox"/>
18	2004041801	WO		2004-05-21	AstraZeneca AB		<input type="checkbox"/>
19	2004041802	WO		2004-05-21	AstraZeneca AB		<input type="checkbox"/>
20	2005066148	WO		2005-07-21	AstraZeneca AB		<input type="checkbox"/>
21	2006014133	WO		2006-02-09	AstraZeneca AB		<input type="checkbox"/>
22	2006091160	WO		2006-08-31	AstraZeneca AB		<input type="checkbox"/>
23	0133323	EP		1985-02-20	The Wellcome Foundation Limited		<input type="checkbox"/>
24	0166302	EP		1986-01-02	Polindustria		<input type="checkbox"/>
25	0289227	EP		1988-11-02	Syntex		<input type="checkbox"/>
26	0283310	EP		1988-09-21	Sankyo Company		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

	27	0624584	EP		1998-08-19	Daiichi	<input type="checkbox"/>
	28	2076403	GB		1981-12-02	Selvi & C.S.p.A.	<input type="checkbox"/>
	29	2210366	GB		1989-06-07	American Home	<input type="checkbox"/>
	30	2431178	DE		1975-01-16	Cemol S.A.	<input checked="" type="checkbox"/>
	31	2900810	DE		1980-07-24	Cassella AG	<input checked="" type="checkbox"/>
	32	2696744	FR		1994-04-15	Laboratoires	<input checked="" type="checkbox"/>
	33	7138230	JP		1995-05-30	Nippon Shoji KK	<input checked="" type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	BILSKY et al., "SNC 80, A selective, nonpeptidic and systematically active opioid delta agonist," J. Pharmacol. Exper. Ther., 1995, Vol. 273, pgs. 359-366	<input type="checkbox"/>
	2	BILSKY et al., "Characterization of enantioners of (+)BW373U86 and related compounds: highly selective non-peptidic delta opioid agonists," Reg. Peptides, 1994, Vol. 54, pgs. 25-26	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EL/

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851	
Filing Date	2006-06-27	
First Named Inventor	Brown	
Art Unit	1731	
Examiner Name		
Attorney Docket Number	101260-1P US	

3	BURKEY et al., "The efficacy of delta-opioid receptor-selective drugs," Medline Abstract for Life Sciences, 1998, Vol. 62, pgs. 1531-1536	<input type="checkbox"/>
4	CALDERON et al., "Probes for narcotic receptor mediated phenomena. 19. Synthesis of... opioid receptor agonist," J. Med. Chem., 1994, Vol. 37, pgs. 2125-2128	<input type="checkbox"/>
5	CALDERON et al., "Probes for narcotic receptor mediated phenomena. 23. Synthesis of... opioid receptor ligands," J. Med. Chem., 1997, Vol. 40, pgs. 695-704	<input type="checkbox"/>
6	CHANG et al., "A novel, potent and selective nonpeptidic delta opioid receptor agonist BW373U86," J. Pharmacol. Exper. Ther., 1993, Vol. 267, pgs. 852-857	<input type="checkbox"/>
7	GREEN, "Protective groups in organic synthesis," 1981, pgs. 267-268 and 331	<input type="checkbox"/>
8	KATRIZKY et al., "Benzotriazole-mediated arylalkylation and heteroarylalkylation," Chem. Soc. Rev., 1994, Vol. 23, pgs. 363-373	<input type="checkbox"/>
9	KINGSBURY et al., "Synthesis of structural analogs of leukotriene B and their receptor binding activity," J. Med. Chem., 1993, Vol. 36, pgs. 3308-3320	<input type="checkbox"/>
10	LOPEZ et al., "Exploring the structure-activity relationships... opioid receptor nonpeptide agonist ligand," J. Med. Chem., 1999, Vol. 42, pgs. 5359-5368	<input type="checkbox"/>
11	NAGASE et al., "The pharmacological profile of delta opioid receptor ligands, (+) and (-) TAN-67 on pain modulation," Medline Abstract for Life Sci., 2001, Vol. 68, pgs. 2227-2231	<input type="checkbox"/>
12	NORTEY et al., "Piperazinyl benzamidines: synthesis and affinity for the delta opioid receptor," Bioorganic & Medicinal Chemistry Letters, 2001, Vol. 11, pgs. 1741-1743	<input type="checkbox"/>
13	PLOBECK et al., "New diarylmethylpiperazines as potent and selective nonpeptidic opioid... with increased in vitro metabolic stability," J. Med. Chem., 2000, Vol. 43, pgs. 3878-3894	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

14	SNYDER et al., "Historical review: opioid receptors," Trends in Pharmacological Sciences, 2003, Vol. 24, pgs. 198-205	<input type="checkbox"/>
15	SUGGS et al., "Facile synthesis of 8-substituted quinolines," J. Org. Chem., 1980, Vol. 45, pgs. 1514-1515	<input type="checkbox"/>
16	TAKEMORI et al., "Selective naltrexone-derived opioid receptor antagonists," Annu. Rev. Pharmacol. Toxicol., 1992, Vol. 32, pgs. 239-269	<input type="checkbox"/>
17	ZHANG et al., "Probes for narcotic receptor mediated phenomena. 26. Synthesis... opioid receptor ligands," J. Med. Chem., 1999, Vol. 42, pgs. 5455-5463	<input type="checkbox"/>
18	Abstract for HU 217619. A corresponding English language PCT application is cited WO86/04584	<input type="checkbox"/>
19	Abstract for HU 215847. A corresponding English language PCT application is cited WO91/07967	<input type="checkbox"/>
20	Filliol, D. et al., "Mice deficient for delta- and mu-opioid receptors exhibit opposing alterations of emotional responses," Nature Genetics, 2000, Vol. 25, pgs. 195-200.	<input type="checkbox"/>
21	WOLFF, M., "Burger's Medicinal Chemistry and Drug Discovery," 5 ed, Part 1, John Wiley & Sons, 1995, pgs. 975-977	<input type="checkbox"/>
22	BANKER, G. et al., "Modern Pharmaceutics," 3 ed, Marcel Dekker, New York, 1996, pgs. 451 and 596	<input type="checkbox"/>
23	WEST, A., "Solid State Chemistry and its Applications," Wiley, New York, 1988, pgs. 358 & 365	<input type="checkbox"/>
24	VIPPAGUNTA, S. et al., "Crystalline Solids," Advanced Drug Delivery Review," Vol. 48, 2001, pgs. 3-26	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

25	DAVIS, MP et al., "Controversies in pharmacotherapy of pain management," Lancet oncol. 6(9), 2005, 696-704	<input type="checkbox"/>
26	PRZEWLOCKI, R. et al., "Opioids in neuropathic pain," Current. Pharm. Des., 11(23), 2005, 2941-2943	<input type="checkbox"/>
27	ADRIAENSEN, H. et al., "Critical review of oral drug treatments for diabetic neuropathic pain-clinical outcomes based on efficacy and safety data from placebo-controlled and direct comparative studies," Diabetes Metab. Res. Rev., 21 (3), 2005, 231-240	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	/Erich Leeser/	Date Considered	01/23/2008
--------------------	----------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /EL/

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10596851
Filing Date	2006-06-27
First Named Inventor	Brown
Art Unit	1731
Examiner Name	
Attorney Docket Number	101260-1P US

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- See attached certification statement.
- Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Jianzhong SHEN, Reg.#48076/	Date (YYYY-MM-DD)	2006-10-18
Name/Print	Jianzhong Shen	Registration Number	48,076

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.